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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,835

09/20/2006

Jacob Hochman

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THE NATH LAW GROUP
112 South West Street
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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

11/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,835	Applicant(s) HOCHMAN, JACOB	
	Examiner ANNE L. HOLLERAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-65 is/are pending in the application.
- 4a) Of the above claim(s) 45, 46 and 51-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44 and 47-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2010; 11/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant is reminded that a properly filed response to an Office action includes a copy of the claims indicating the status identifiers, such as "Previously Presented" and "Withdrawn", etc.

Claims 40-65 are pending.

Claims 45, 46, and 51-65, drawn to non-elected inventions, are withdrawn from consideration.

Claims 40-44 and 47-50 are examined on the merits.

Claim Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-44 and 47-50 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant points to page 38 of the published present application for support of the phrase "high level of expression", and to page 6 of the present application, and argues that a set of cancer patients is used to determine the standards and then these standards are used for future diagnosis of breast cancer in other subjects susceptible to having breast cancer. This does not

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persuade the examiner to withdraw the current rejection of the claims under 35 USC 112, 2nd paragraph, because applicant does not address the argument made in the previous Office action where it was asked how can one use a standard prepared from tumor samples if the terms "high level of expression" and "high degree of binding" are terms that are relative to a standard. With respect to "suspicious area in the breast", applicant's argument is not found persuasive because pointing to an example does not apprise one of the scope of the claim. Therefore, the rejection is maintained for the reasons of record. The grounds for the rejection are repeated below:

Claims 40 and 47 refer to "high level of expression" or "high degree of binding", which are phrases that are unclear because the terms "high level" or "high degree" appear to be relative to a standard. However, the specification provides a description of "high level of expression", where the description includes a method of preparing a standard by determining the level of expression of p14 peptide present in a sample obtained from a plurality of patient positively diagnosed as having breast cancer (see page 6, line 16). Because the claimed methods have the purpose of diagnosing breast cancer, it is not clear how samples from breast cancer patients may be used as standards, and it is not clear in light of the specification what is meant by "high level of expression" or "high degree of binding".

Claims 42 and 48 are indefinite because of the term "suspicious area in the breast". This term appears to be a subjective definition for an area of the breast, and is open to many interpretations. Therefore, the scope of the claims is not clear.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40-43 and 47-49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pogo (US 6,040,146; issued Mar. 21, 2000) in view of Hoch-Marchaim (Hoch-Marchaim, H., Virology, 313: 22-32, 2003; of record), and further in view of Melana-I (Melana, S.M., et al. Clinical Cancer Research, 7: 283-284, 2001) for the reasons of record.

The grounds of rejection are set forth below:

Pogo teaches a method of detecting breast cancer by the method of detecting peptides encoded the MMTV env gene, and fragments thereof (column 6, line 63 – column 7, line 53). Pogo fails to teach the specific fragment of p14, which is the lead peptide of MMTV Env precursor protein. Pogo fails to characterize the breast tissue as fresh biopsy section, cryo-section or paraffin embedded section.

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Hoch-Marchaim teaches that p14 is the leader peptide of MMTV Env precursor protein, and that it is present in T cell lymphomas (see abstract; see page 30).

Melana-I teaches that paraffin embedded section of breast tissue from breast cancer or normal breasts may be used in the detection of MMTV-like env sequences (see page 283).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Pogo with those of Hoch-Marchaim and Melana-I to make the claimed method of diagnosing breast cancer in a subject of or screening samples. One would have been motivated to use the methods and antibodies of Hoch-Marchaim because Hoch-Marchaim demonstrates p14 is a common protein in MMTV-derived T cell lymphomas. One would have had a reasonable expectation of success in combining the teachings of the cited references to arrive at the claimed methods because MMTV is associated with breast cancer, as taught by Pogo.

Claims 40-42, 44, 47, 48 and 50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pogo (US 6,040,146; issued Mar. 21, 2000) in view of Hoch-Marchaim (Hoch-Marchaim, H., Virology, 313: 22-32, 2003; of record), and further in view of Melana-II (Melana, S.M. et al. Medicina (B Aires), 62(4): 323-327, 2002; abstract only) for the reasons of record. The grounds of rejection are set forth below:

Pogo teaches a method of detecting breast cancer by the method of detecting peptides encoded the MMTV env gene, and fragments thereof (column 6, line 63 – column 7, line 53). Pogo fails to teach the specific fragment of p14, which is the lead peptide of MMTV Env

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precursor protein. Pogo fails to teach further detecting MMTV env sequences in a blood sample from a breast cancer patient.

Hoch-Marchaim teaches that p14 is the leader peptide of MMTV Env precursor protein, and that it is present in T cell lymphomas (see abstract; see page 30).

Melana-II teaches that in the peripheral blood mononuclear cells of breast cancer patients, MMTV expression is detectable (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Pogo with those of Hoch-Marchaim and Melana-II to make the claimed method of diagnosing breast cancer in a subject of or screening samples. One would have been motivated to use the methods and antibodies of Hoch-Marchaim because Hoch-Marchaim demonstrates p14 is a common protein in MMTV-derived T cell lymphomas. One would have had a reasonable expectation of success in combining the teachings of the cited references to arrive at the claimed methods because MMTV is associated with breast cancer, as taught by Pogo.

Answer to Arguments:

Applicant argues that there would be no reasonable expectation of success that the cited references could be modified to arrive at the presently claimed subject matter, because in various cell lines acceptable as models of breast cancer the presence of p14 was not detected to be used as the marker for diagnosing human breast cancer in accordance with the presently claimed subject matter. Applicant states that in Hoch-Marchaim 1998 the present inventor described that p14 is localized to the nucleoli of T-cell lymphomas that harbor the virus and that Hoch-

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Marchaim 1998 demonstrates that MMTV-positive cells of non-lymphocytic origin are devoid of both p14 and p21. This is not found persuasive because Hoch-Marchaim 1998 was not cited, but instead Hoch-Marchaim 2003 was cited in the previous Office action. Additionally, Hoch-Marchaim 1998 bases the statement that p14 is not found in MMTV-positive cells of non-lymphocytic origin on a small number of samples. When this is considered against the weight of the teachings of the cited references, that of Pogo that detecting MMTV env gene peptides and fragments thereof is useful for detecting breast cancer, that of Hoch-Marchaim 2003 provides a monoclonal antibody that detects a specific fragment of MMTV env gene peptides and that of Malena-I, that paraffin embedded sections of breast tissue from breast cancer or normal breasts may be used in the detection of MMTV-like env sequences; or that of Malena-II, that in peripheral blood mononuclear cells of breast cancer patients, MMTV expression is detectable, one of skill in the art has a reasonable expectation of success in modifying the methods of Pogo to make the claimed methods. Therefore, the rejections are maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached on (571) 272-0839. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran

Patent Examiner

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643